UNITED STATES DEPARTMENT OF COMMERCE
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09/016,159 VB

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
09/016,159	01/30/98	LEE J	07004-002002

HM22/1126

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EXAMINER	
FITZGERALD, D	
ART UNIT	PAPER NUMBER
1646	11

DATE MAILED: 11/26/99

Below is a communication from the EXAMINER in charge of this application

COMMISSIONER OF PATENTS AND TRADEMARKS

ADVISORY ACTION

☒ THE PERIOD FOR RESPONSE:

a) ☐ is extended to run _____ or continues to run _____ from the date of the final rejection

b) ☒ expires three months from the date of the final rejection or as of the mailing date of this Advisory Action, whichever is later. In no event however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition , and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

☐ Appellant's Brief is due in accordance with 37 CFR 1.192(a).

☐ Applicant's response to the final rejection, filed _____ has been considered with the following effect, but it is not deemed to place the application in condition for allowance:

1. ☒ The proposed amendments to the claim and /or specification will not be entered and the final rejection stands because:

   a. ☐ There is no convincing showing under 37 CFR 1.116(b) why the proposed amendment is necessary and was not earlier presented.

   b. ☒ They raise new issues that would require further consideration and/or search. (See Note).

   c. ☒ They raise the issue of new matter. (See Note).

   d. ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.

   e. ☐ They present additional claims without cancelling a corresponding number of finally rejected claims.

   NOTE: See attached -

2. ☐ Newly proposed or amended claims _____ would be allowed if submitted in a separately filed amendment cancelling the non-allowable claims.

3. ☐ Upon the filing an appeal, the proposed amendment ☐ will be entered ☐ will not be entered and the status of the claims will be as follows:

   Claims allowed: _____
   Claims objected to: _____
   Claims rejected: _____

   However;

   ☐ Applicant's response has overcome the following rejection(s): _____

4. ☐ The affidavit, exhibit or request for reconsideration has been considered but does not overcome the rejection because _____

5. ☐ The affidavit or exhibit will not be considered because applicant has not shown good and sufficent reasons why it was not earlier presented.

☐ The proposed drawing correction ☐ has ☐ has not been approved by the examiner.

☐ Other

Procedural matters

Receipt of the duplicate copy of the reply originally filed on 19 August 1999 is acknowledged. Because the reply was filed with a certification under 37 C.F.R. § 1.8 indicating that it was mailed on 14 August 1999, the Office will treat the reply as having been filed within two months of the final rejection, which was mailed on 14 June 1999. The shortened statutory period for response to the final rejection will consequently expire as of the mailing date of the present communication, and the fee for any extension of time which applicant may request would be calculated from the latter date. Applicant is reminded, however, that the period for response to the final rejection may not be extended beyond the six-month statutory maximum from the mailing date of the final Office action.

Denial of entry of the amendment

The amendment and remarks filed 19 August 1999 will not be entered because they would compel consideration of new grounds of rejection.

The rationale for admitting the recitation of explicit EPO-R sequences into the disclosure in this and the several parent applications was that it was understood in the art that there was a single human EPO-R amino acid sequence. Thus the generic description of "the human EPO receptor" as set forth in the disclosure as filed would necessarily have conveyed to the artisan that the sequence set forth in the (first) sequence listing was the only one that could have been contemplated. Consideration of the remarks now filed would lead to the conclusion that the rationale previously relied upon was in error and thus that the sequence listing (original or revised) should be objected to as introducing new matter into the disclosure. For like reasons, entry of the proposed amendments to the claims would compel consideration of new grounds of rejection under 35 U.S.C. § 112, first paragraph. Amendment of the recited sequences would additionally compel consideration of new grounds of rejection under 35 U.S.C. § 103.

Applicant's arguments concerning the outstanding rejection under § 112, first paragraph, would not be persuasive. It is irrelevant that the artisan would have understood that bacterial expression products are unglycosylated because the genus of unglycosylated polypeptides is broader than the genus of bacterial expression products. Moreover, the relevant issue is whether the claimed invention is described, not enabled, as applicant's remarks suggest.

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22 November 1999